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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,590	07/06/2001	William D. Husc	P-IX 4102	5192
41552	7590	04/20/2005	EXAMINER	
MCDERMOTT, WILL & EMERY 4370 LA JOLLA VILLAGE DRIVE, SUITE 700 SAN DIEGO, CA 92122			BLANCHARD, DAVID J	
			ART UNIT	PAPER NUMBER

1642

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/900,590	HUSE, WILLIAM D.	
	<b>Examiner</b>	<b>Art Unit</b>	
	David J. Blanchard	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 80-92 is/are pending in the application.
- 4a) Of the above claim(s) 80-84 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 85-92 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Exhibit A.

*HL*

### **DETAILED ACTION**

1. Claims 1-79 are cancelled.

Claims 80-84 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

2. Claims 85-92 are under examination.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. This Office Action contains New Grounds of Objection.

### ***Objections/Rejections Withdrawn***

5. The objections to the specification because Table 8 is missing and Tables 8-10 are presented consecutively and for presenting two separate Table 10's are withdrawn in view of the preliminary amendment filed 7/6/2001, which was not previously considered by the examiner.
6. The rejection of claims 85-92 under 35 U.S.C. 112, second paragraph, as being indefinite for reciting "enhanced antibody" and "functional fragments thereof" is withdrawn in view of applicant's arguments and in view of part (c) of claim 85, which defines an "enhanced antibody" as a variant antibody having an association rate to an antigen that is 4-fold higher compared to the rate of said parent antibody.
7. The rejection of claims 92 under 35 U.S.C. 112, second paragraph, as being indefinite for reciting "grafted antibody" is withdrawn in view of applicant's arguments and the definition at page 11, lines 19-24 of the specification.

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8. The rejection of claims 85-87, 90 and 91 under 35 U.S.C. 102(b) as being anticipated by Shier et al is withdrawn in view of applicant's arguments, i.e., Shier does not teach a variant antibody wherein the association rate constant ( $K_{on}$ ) is 4-fold greater than the association rate constant of the parent antibody.

9. The rejection of claims 85-91 under 35 U.S.C. 102(e) as being anticipated by Marks et al is withdrawn in view of applicant's arguments, i.e., Marks does not teach a variant antibody wherein the association rate constant ( $K_{on}$ ) is 4-fold greater than the association rate constant of the parent antibody.

10. The rejection of claims 85-87 under 35 U.S.C. 102(b) as being anticipated by Yelton et al is withdrawn in view of applicant's arguments, i.e., Yelton does not teach a variant antibody wherein the association rate constant ( $K_{on}$ ) is 4-fold greater than the association rate constant of the parent antibody.

11. The rejection of claims 85-92 under 35 U.S.C. 103(a) as being unpatentable over Shier et al in view of Foote et al is withdrawn in view of applicant's arguments, i.e., Shier does not teach a variant antibody wherein the association rate constant ( $K_{on}$ ) is 4-fold greater than the association rate constant of the parent antibody.

### ***Response to Arguments***

12. The objection to abstract for exceeding the maximal length of 150 words is maintained.

The response filed 1/24/2005 did not address the objection to the abstract and the objection is maintained.

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13. The rejection of claims 85-92 under 35 U.S.C. 112, second paragraph, as being indefinite for reciting "modifying" is maintained.

The response filed 1/24/2005 has been carefully considered, but is deemed not to be persuasive. The response argues that "modifying" is clear and definite and has an ordinary and plain meaning which applicant has not deviated from. In response to this argument, applicant has not pointed to anything in the claims or specification, which clearly defines the meaning of the term and sets forth the metes and bounds of the claimed invention. The ordinary and plain meaning of the term "modifying" means to make basic or fundamental changes in, often to give a new orientation to or serve a new end (see Exhibit A attached to the back of this Office Action). Thus, the term "modifying" without more precise claim language that particularly points out the direction, requisite degree and endpoint of the modification does not clearly set forth the metes and bounds of the claimed invention for one of skill in the art. For example, the term "modifying" encompasses amino acid substitutions, deletions, additions, or PEGylation, or aglycosylation, or immunoconjugates or antibody mimetics which have disparate functions, effects and different endpoints and one of skill in the art would not know which of these "modifications" or functions are required by the claims.

14. The rejection of claim 85 under 35 U.S.C. 112, second paragraph, as being indefinite for reciting "the rate" is maintained.

The response filed 1/24/2005 has been carefully considered, but is deemed not to be persuasive. The response states that claim 85 has been amended to correct this

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informality. In response, claim 85 has not been amended to correct the rejection of the claim as being indefinite for lack of antecedent basis and the rejection is maintained.

15. The rejection of claims 85-89 and 92 under 35 U.S.C. 102(b) as being anticipated by Deng et al is maintained.

The response filed 1/24/2005 has been carefully considered, but is deemed not to be persuasive. The response argues that Deng does not teach variant antibodies wherein the association rate constant ( $K_{on}$ ) is measured or wherein a variant antibody is produced that has a 4-fold higher or greater association rate constant ( $K_{on}$ ) compared to the association rate of the parent antibody. In response to this argument Deng et al teach variant antibodies wherein the association rate constant ( $K_{on}$ ) is measured and the association rate constant of variant antibodies B3-19, B4-3, B5-1, B5-5, B5-6, B5-8 and B5-12 are greater than 4-fold compared to the association rate of the parent antibody (WT) (see Table 3).

Therefore, the rejection of claims 85-89 and 92 under 35 U.S.C. 102(b) as being anticipated by Deng et al is maintained.

### ***New Grounds of Objection***

16. The disclosure is objected to because of the following informalities:

The first line of the specification is objected to because the instant application is a CIP and not a CON of prior application no. 09/016,061 (now U.S. Patent 6,596,850), filed 1/30/1998 (see below). Applicant is required to update the first line of the

specification indicating that the instant application is a CIP of prior application no. 09/016,061.

Prior USSN 09/016,061 does not disclose a method for producing an enhanced antibody or fragment thereof that has an association rate constant ( $k_{on}$ ) that is 4-fold higher than the  $k_{on}$  of the parent antibody and wherein the enhanced antibody has a  $k_{on}$  that is  $6.8 \times 10^5 \text{ M}^{-1} \text{ sec}^{-1}$  or higher, or an enhanced antibody having a  $k_{on}$  that is 4-fold higher than the  $k_{on}$  of the parent antibody and wherein the  $k_{on}$  that is  $6.8 \times 10^5 \text{ M}^{-1} \text{ sec}^{-1}$  or higher and having an association constant ( $K_a$ ) that is  $2.0 \times 10^9 \text{ M}^{-1}$  or higher.

If applicant disagrees with the examiner's factual determination above, it is incumbent upon the applicant to provide the specific page numbers that specifically supports the particular claim limitations of the instant claims which applicant considers to have been in possession and fully enabled prior to June 6, 2001.

Appropriate correction is required.

### ***Conclusion***

17. No claim is allowed.
18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,  
David J. Blanchard  
571-272-0827



LARRY R. HELMS, PH.D.  
PRIMARY EXAMINER



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One entry found for **modify**.

**Thesaurus**

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modify

Main Entry: **mod·i·fy**

Pronunciation: 'mä-d&-"fI

Function: *verb*

Inflected Form(s): **-fied; -fy·ing**

Etymology: Middle English *modifien*, from Middle French *modifier*, from Latin *modificare* to measure, moderate, from *modus*

*transitive senses*

1 : to make less extreme : **MODERATE**

2 a : to limit or restrict the meaning of especially in a grammatical construction b : to change (a vowel) by umlaut

3 a : to make minor changes in b : to make basic or fundamental changes in often to give a new orientation to or to serve a new end <the wing of a bird is an arm *modified* for flying>

*intransitive senses* : to undergo change

**synonym** see **CHANGE**

- **mod·i·fi·abil·i·ty** /'mä-d&-"fI-&-"bi-l&-tE/ *noun*

- **mod·i·fi·able** /'mä-d&-"fI-&-b&l/ *adjective*

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